

The HIPAA Privacy Rule: Potential Impact on the Sharing of Immunization Data

Gail Horlick, M.S.W., J.D.

2003 GPRA Medicaid Childhood
Immunization Project Annual Meeting

Baltimore, MD

April 3, 2003



Overview

- Background and status of Privacy Rule
- Scope of Privacy Rule
- Disclosure to and from public health
- Disclosure to schools
- Implementation decisions impacting public health practice
- Summary
- Resources



Background

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
 - Requires Congress to enact privacy legislation by 8/99 or HHS to promulgate regulations
 - Requires development of standards for transactions and code sets
 - Requires development of security standard



Current Status of Regulations

- Amendments to final HIPAA Privacy Rule published 8/14/02
 - Compliance date 4/14/03
 - Small health plans 4/14/04
- Standards for transactions and code sets
 - Rule published 8/2000
 - Compliance date 10/16/02; 10/16/03 if extension filed by 10/15/02
- Standard for security published 2/13/03
 - Compliance date 4/05



Scope of HIPAA Privacy Rule (1)

- Rule applies to Covered Entities (CE):
 - Health plans
 - Health care clearinghouses
 - Health care providers (those who transmit certain health claims information electronically)
- Many provisions of rule apply indirectly to Business Associates (BA) hired to perform functions or activities on behalf of CE
 - e.g. legal or accounting services, utilization review, claims processing
 - CE needs satisfactory assurance, usually a contract or MOU, that BA will safeguard information



Scope of HIPAA Privacy Rule (2)

- Rule governs the use and disclosure of Protected Health Information (PHI)
- Protects:
 - all individually identifiable health information
 - in any form, electronic or non-electronic
 - that is held or transmitted by a covered entity or its BA



Relationship Of Privacy Rule To Federal and State Laws (1)

- CE subject to other federal laws and regulations (e.g. Privacy Act of 1974)
- Privacy rule preempts state laws that are contrary to rule (45 CFR §160.203)
 - Limited exceptions such as fraud and abuse
- Does not preempt more stringent state privacy laws
 - Provides a floor



Relationship Of Privacy Rule To Federal and State Laws (2)

- Does not preempt laws “for the conduct of public health surveillance, investigation, or intervention...” (45 CFR §160.203(a)(2)(c))
- Excludes records covered by Family Educational Rights and Privacy Act (FERPA)



Intent Of Rule Regarding Public Health

Analysis of comments in preamble to privacy rule refers to mandate in HIPAA:

“Nothing in this part shall be construed to invalidate or limit the authority, power or procedures established under any law providing for the reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention.”



Disclosure by Covered Entities (1)

- Providers who transmit PHI electronically are CE
- CE must obtain written authorization for disclosures of PHI EXCEPT:
 - For treatment, payment or health care operations (TPO)
 - To individual
 - Exceptions specifically listed in rule



Disclosure by Covered Entities (2)

CE must:

- disclose minimum amount of information necessary to achieve intended purpose
 - Does not apply to disclosures for treatment or to individual
- keep track of disclosures to non CE
- provide accounting of disclosures if requested



Disclosure To Public Health (1)

- Providers may disclose PHI to public health authorities without authorization:
 - If reporting is required by law (45 CFR §164.512(a)(1)) **and/or**
 - For certain public health activities and purposes (45 CFR §164.512(b)(1)(i))
 - Other specified purposes
- Specific mandate to report not required
- State and local laws still apply



Disclosure To Public Health (2)

Provider may disclose PHI for activities and purposes to:

“...a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease,....the conduct of public health surveillance, public health investigations, and public health interventions...” (§164.512(b)(1)(i))



Public Health Authority

Public health authority means:

- an agent or authority of the US, a State, a territory, a political subdivision of a State or territory, or an Indian tribe,
- or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency, or its contractors or persons or entities to whom it has granted authority,
- that is responsible for public health mandates as part of its official mandate (45 CFR §164.501)



Disclosure to Schools

- School may be considered public health authority for limited purpose, to extent that it is authorized to collect or receive information for public health purposes, e.g. to comply with school immunization laws
- Providers may be able to disclose PHI to schools without authorization
- Consistent with intent of Rule
- Check with your legal counsel



Disclosure From Public Health

- Depends on whether individual entity is a CE
 - Doctors, nurses, and other providers of direct service in state and local health departments are CE
 - Payers (e.g. Medicaid) are CE
- CE must comply with Privacy Rule
- Privacy Rule does not govern use and disclosure of information by non CE
 - State and local laws still apply



HIPAA Implementation Decisions Impacting Public Health

- Many legal entities (e.g. state DHHS) perform covered functions (e.g. direct service, payment) and non-covered functions (e.g. registries, surveillance, licensing)
- Legal entity with covered and non-covered functions can choose to be a hybrid entity or entire legal entity can function as CE
 - Decision may depend on how entity is structured
- Legal entity may not perform covered functions and not be CE



Hybrid Entity

- Hybrid entity means a single legal entity
 - That is a CE
 - Whose business activities include both covered and non-covered functions; and
 - That designates health care components...(45 CFR §164.504)
- Health care components must comply with appropriate provisions of Privacy Rule
- Non health care components not required to comply with most provisions
- CE that does not designate health care components, is subject to Privacy Rule in entirety



Why not become a hybrid?

- Hybrid entities must create adequate separation (e.g. firewalls) between health care components and other components
- Transfer of PHI by health care component to non health care component is disclosure
- Health care components must keep track of disclosures



What if an entire legal entity decides to function as a CE?

- CEs can exchange information for coordination of benefits
- Covered functions (e.g. direct service) will have to comply with Rule (e.g. notice to patients, tracking disclosures)
- Programs or services that would not traditionally be considered covered (e.g. registries) will have to comply with applicable provisions of Rule for use and disclosure of PHI
 - Need authorization unless disclosure is for TPO, to individual, or an exception
 - Must track disclosures



Summary: Disclosure to Public Health Under HIPAA

- Providers (CE) can disclose PHI for public health purposes without authorization if the information is the minimum necessary to meet the intended purpose
 - Specific mandate to report is not required
 - State and local laws still apply
 - Must track disclosures



Summary: Disclosure from Public Health Under HIPAA

- Determine whether legal entity is a CE (seek legal counsel)
 - Non CE are not bound by HIPAA
- If legal entity is a CE:
 - Is it a hybrid? If so, determine if program is a health care component or non health care component
 - If entire entity is a CE, does state law address disclosure? If not, is disclosure allowed for treatment or treatment activity of health care provider? Is an authorization required?



For More Information: CDC Resources

- CDC/ ATSDR Privacy Rule Homepage:
<http://www.cdc.gov/privacyrule>
 - MMWR
 - Q can be submitted to CDC Privacy Rule Coordinator
- National Immunization Program website:
<http://www.cdc.gov/nip/registry>
 - Click on Privacy, Confidentiality, Security & Legislation



For More Information: Office for Civil Rights

- OCR website:
<http://www.hhs.gov/ocr/hipaa>
- Search and view FAQs and updated guidance document (12/3/02) at
<http://www.hhs.gov/ocr/hipaa/assist.html>
 - Disclosure to public health, pages 77-84



Contact Information

Gail Horlick, M.S.W., J.D.

Program Analyst

CDC National Immunization Program

1600 Clifton Rd. NE, MS E-62

Atlanta, Ga. 30333

phone: 404-639-8345

fax: 404-639-8171

email: gyh6@cdc.gov

